IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IDENIX PHARMACEUTICALS LLC, UNIVERSITA DEGLI STUDI DI CAGLIARI, CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE and L'UNIVERSITE MONTPELLIER,

Plaintiffs,

v.

GILEAD SCIENCES, INC. and GILEAD PHARMASSET LLC,

Defendants.

C.A. No. 13-1987-LPS

[redacted]

REDACTED VERSION

IDENIX PHARMACEUTICALS LLC, UNIVERSITA DEGLI STUDI DI CAGLIARI, CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE and L'UNIVERSITE MONTPELLIER,

Plaintiffs,

v.

GILEAD PHARMASSET LLC,

Defendant.

C.A. No. 14-109-LPS

[redacted]

REDACTED VERSION

IDENIX PHARMACEUTICALS LLC UNIVERSITA DEGLI STUDI DI CAGLIARI,

Plaintiffs,

v.

GILEAD SCIENCES, INC.

Defendant.

C.A. No. 14-846-LPS

[redacted]

REDACTED VERSION

GILEAD'S OPENING BRIEF IN SUPPORT OF ITS MOTION TO PHASE TRIAL

Dated: November 18, 2016

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I. NATURE AND STAGE OF THE PROCEEDINGS

Through its pre-trial disclosures, Idenix has signaled its intent to feature at trial many prejudicial and confusing pieces of evidence that have no bearing on liability and that—to the extent they have any relevance—would be relevant only to issues of damages and willful infringement. In particular, Idenix intends to highlight evidence regarding the extremely high revenues for Gilead's breakthrough therapy, including emotionally charged evidence on the pricing of that therapy, and regarding purported "copying" of a feature of Idenix compounds by Pharmasset, Gilead's predecessor. The "copying" allegation Idenix wants to present to the jury is simply untrue and, if necessary, Gilead will prove at trial that neither it nor Pharmasset copied anything from Idenix. However, as discussed in Gilead's pending motions *in limine*, much of the evidence Idenix wants to present is irrelevant even if it were true—which it is not—and should be excluded entirely. To the extent some portion of it is relevant and admissible, it is relevant only to damages and willfulness and introducing it while the jury is still deciding the question of Gilead's liability creates significant risk of unfair prejudice to Gilead by making it more difficult for the jury to impartially consider only the evidence related to liability. Gilead, therefore, requests that the Court phase trial.

In that phased trial, Gilead should go first, presenting its case for invalidity. Following this Court's recent claim construction order, Gilead has agreed not to dispute that, if the claims of the '597 patent are valid, they cover doctors and patients using sofosbuvir. Accordingly, the only liability issue to be decided at trial is whether Idenix's patent is invalid, an issue on which Gilead bears the burden of proof. Thus, Gilead should first present its case on invalidity, followed by Idenix's opposition and Gilead's rebuttal. Then, only if the jury finds Idenix's patent valid, Idenix can present its damages and willfulness case to the same jury, followed by Gilead's opposition and Idenix's rebuttal on damages and willfulness. Overall trial time would

not be affected. This approach not only avoids the unfair prejudice to Gilead of having potentially confusing and inflammatory evidence presented to the jury during the liability phase, but also promotes judicial efficiency by avoiding the necessity of taking the jury's time presenting damages and willfulness evidence, at all, if the jury first determines there is no liability. Thus, because of the significant benefits of phasing, and the lack of any prejudice to Idenix from phasing, Gilead requests that this Court phase trial.

II. BACKGROUND

In its pre-trial disclosures over the past several weeks, Idenix has revealed its intent to focus its trial presentation on issues that are unrelated to liability and that, if they have any relevance, are relevant only to issues of damages and willfulness. That evidence includes: (1) emotionally charged evidence regarding the pricing of Gilead's accused products, criticism of that pricing, and purported patient access issues resulting from that pricing; (2) evidence regarding the unprecedented success of the accused products and the resulting unprecedented revenues associated with those products; (3) unsubstantiated allegations that Pharmasset "copied" the concept of 2'methyl up from Idenix years before the '597 patent issued and before the claims as asserted in this case existed; and (4) inflammatory evidence of [redacted], unrelated to the patents in suit. Much of the above-described evidence is already the subject of pending motions *in limine*, and should not be admitted into evidence at any time. To the extent some portion of the above-described evidence is relevant, its relevance is limited to issues of damages and willfulness, and allowing its introduction while the jury is deciding liability could prejudice Gilead and confuse the jury.

When it became apparent during the parties' pre-trial exchanges (a process completed only yesterday) that Idenix intended to feature the above described evidence at trial, Gilead

requested that Idenix agree to phase trial so as to have the jury first decide liability first and then, only if the jury decides Gilead is liable, have the jury decide the issues of damages and willfulness. On November 17, Idenix refused Gilead's request, after which Gilead immediately filed this motion.[1]

III. LEGAL STANDARD

A court may phase any trial "[f]or convenience, to avoid prejudice, or to expedite and economize." Fed. R. Civ. P. 42(b). Courts have broad discretion to order phased trials under this rule. *Gardco Mfg., Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1211–12 (Fed. Cir. 1987). A phased trial is warranted if it "will avoid prejudice, conserve judicial resources, and enhance juror comprehension of the issues presented in the case." *Lab. Skin Care, Inc. v. Ltd. Brands, Inc.*, 757 F. Supp. 2d 431, 441 (D. Del. 2010) (quoting *Enzo Life Scis., Inc. v. Digene Corp.*, 2003 WL 21402512, at *4 (D. Del. June 10, 2003)).

"In deciding whether one trial or separate trials will best serve the above factors [for Rule 42(b)] the major consideration is directed toward the choice most likely to result in a just final disposition of the litigation." *Ciena Corp. v. Corvis Corp.*, 210 F.R.D. 519, 521 (D. Del. 2002) (internal citation omitted). In patent cases, phasing liability and damages/willfulness is not uncommon, particularly when the damages or liability issues are complex and extensive evidence would be necessary. *See E.I. Dupont de Nemours & Co. v. Phillips Petroleum Co.*, 656 F. Supp. 1343, 1346 (D. Del. 1987); *Enzo Life*, 2003 WL 21402512, at *5 (citations omitted). Thus, phasing a trial acts to "simplify the issues in patent cases and to maintain manageability of the volume and complexity of the evidence presented to a jury." *Ciena Corp.*, 210 F.R.D. at 521.

[1] As described in the attached declaration of Joseph B. Warden, counsel for Gilead and Idenix, including Delaware and lead counsel, met and conferred regarding Gilead's request for phasing before Gilead filed this motion, but were unable to reach agreement.

IV. ARGUMENT

A. Phasing Trial Will Avoid Unfairly Prejudicing Gilead Through the Presentation of Potentially Inflammatory Evidence That, At Most, Is Relevant Only to Damages and Willfulness

1. Evidence Idenix seeks to introduce re damages is not relevant to liability and would prejudice Gilead and confuse the jury if introduced while the jury is deciding that issue

This is not a typical patent case where damages can be easily tried with liability through the testimony of a damages expert, with little or no prejudice to the defendant. In this case, Idenix is seeking [redacted] would be the largest patent damages verdict in U.S. history—by a wide margin. (*See* Warden Decl. Ex. 1 at 5 (listing ten largest patent damages verdicts in U.S. history).) The sheer magnitude of that number, alone, is enough to prevent the jury from viewing the evidence of liability from a neutral perspective.

Additionally, Idenix has made it clear that in support of its damages claim it intends to present evidence related to the pricing of the accused products, criticism of the pricing of the accused products, and the impact that pricing has on patient access. (*See* D.I. No. 454-7 (Idenix's Opp. to Gilead's Motion *in Limine* No. 3.)) As already described in Gilead's Motion *in Limine* No. 3, most of that evidence is highly prejudicial and entirely irrelevant and should be excluded. To the extent the Court allows Idenix to introduce some pricing evidence to support its damages claim, however, list prices are not the prices actually paid by customers and introduction of evidence regarding those list prices requires Gilead to respond with evidence regarding the confidential discounts it provides, the drugs it gives away for free, and the greater expense of the far inferior regimens that sofosbuvir replaced. This evidence is not relevant even during a damages phase of the trial, let alone to the jury's determination of the validity of

Idenix's patent. Such evidence also requires the testimony of multiple fact witnesses above and beyond the traditional testimony of an expert witness on damages.

In addition, if evidence of damages is not phased, in order to prevent jury confusion, each time such evidence is introduced, the Court will need to give the jury a limiting instruction that such evidence is not to be considered for liability, but only for damages. While such an instruction may ameliorate jury confusion, it would only serve to heighten the prejudicial nature of such evidence by repeatedly reminding the jury about damages before liability has been determined.

That is why, under nearly identical circumstances, the California court in the related trial between Gilead and Idenix's parent, Merck, *sua sponte* elected to phase trial in the manner Gilead requests. There, in light of the fact that infringement was not an issue (as is the case here) and as a result of the court's concern about the prejudicial nature of some of Merck's damages related evidence, the court explained that "it appears to me that a reasonable way of proceeding would be to phase the presentation of the case to the jury. . . . It seems like it would be reasonable to have Gilead present the jury portion of the case evidence first and have the jury deliberate on the—all of the invalidity issues that go to the jury. And then after we have that verdict, to then go on to damages." (Warden Decl. Ex. 2 at 5:3-14.) As the court further explained, phasing would have the benefit of "protect[ing] Gilead from some of the evidence that it felt might be prejudicial to it if presented during its invalidity presentation." (*Id.* at 5:18-20.) As a result, that court phased trial. Because, as here, infringement was not at issue, that court ordered that Gilead would first present its case for invalidity, and then Merck would respond.

Notably, Idenix's damages case is virtually *identical* to Merck's—using the same expert, relying on exactly the same licenses, to arrive at exactly the same damages opinion—only now,

with passage of time, the revenues and requested damages are even larger than in the Merck case. Thus, the benefit of bifurcation here would be at least as great as in the Merck case, and likely greater because—unlike here (as discussed below)—the Merck case did not include a claim for willful infringement. As the Court did in California, therefore, this Court should phase trial with Gilead presenting its case for invalidity first and then proceeding to the damages phase only if the jury finds Gilead failed to meet its burden on liability.

2. Evidence Idenix seeks to introduce re "copying" is not relevant to liability and would prejudice Gilead if introduced while the jury is deciding that issue

The evidence Idenix seeks to introduce regarding alleged "copying" is not relevant to liability. Idenix's assertion that it could be relevant to Gilead's § 112 defenses is wrong, because both the enablement and written description requirements under § 112 turn on the disclosure in "the four corners of the specification" of Idenix's '597 patent. *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010). Apart from this, the "copying" alleged by Idenix took place in 2002-2003, years before the asserted claims issued in 2009. Thus, even if Idenix's allegations of "copying" in 2002-2003 were true, they have no impact on whether Idenix's claims, as issued in 2009, were sufficiently described and enabled. Those allegations cannot show that Pharmasset viewed Idenix's specification as sufficiently describing or enabling the issued claims, because neither Pharmasset nor anyone else could have even seen the claims.

To the extent Idenix's allegations of copying could be relevant to willful infringement—which, for the reasons articulated in Gilead's Motion in Limine No. 2, they are not—allowing those allegations to be heard by the jury during the liability phase would be highly prejudicial. "[W]illfulness is an intrusive and inflammatory issue to discover and try" and "requires quantitatively and qualitatively different proof than does infringement, and therefore, need not be tried at the same time." *Robert Bosch LLC v. Pylon Mfg. Corp.*, 2009 WL 2742750, at *1 (D.

Del. Aug. 26, 2009). Willfulness, likewise, requires quantitatively and qualitatively different proof than does defending against a claim of invalidity. For example, willfulness requires determining whether a defendant acted as a "wanton and malicious pirate" or with "egregious infringement behavior," *Halo Elec. Inc. v. Pulse Elec., Ins.*, 136 S. Ct. 1923, 1932 (U.S. 2016), which is not an issue in determining validity.

Because any alleged willful infringement is a separate inquiry from liability, the jury does not need to hear evidence related to alleged willfulness to decide issues relating to liability, and doing so could prejudice Gilead, confuse the jury, and waste time. This is particularly true where, as here, the only liability issue to be decided is whether Idenix's patent is invalid and where the evidence Idenix intends to present to the jury in support of its willfulness allegations long predates the issuance of the patent-in-suit in 2009.

Additionally, although Idenix's allegation of copying is untrue and, if necessary, Gilead will disprove it, doing so will require an extensive presentation by both sides on issues totally unrelated to liability, which would be both confusing and prejudicial. That presentation will require not merely an examination of what Pharmasset knew, when it knew it, and how if at all it used any knowledge allegedly imparted by Idenix, but also a lengthy detour into the [redacted]. (*See, e.g.*, D.I. 420.) For the reasons described in Gilead's Motion *in Limine* No. 2, such a detour is unwarranted at any time. Presentation of that evidence would be *particularly* prejudicial if it were to occur while the jury is still considering issues of liability. At that time, there is danger that emphasis on evidence that Pharmasset supposedly copied from Idenix will confuse the jury and lead it to give less weight to the legally relevant, but less easily accessible, scientific evidence regarding the sufficiency of Idenix's patent disclosures.

Confusing the jury appears to be precisely what Idenix hopes for, as evidenced by Idenix's argument that copying is relevant to Gilead's § 112 defenses because it shows the "ease with which Pharmasset was able to understand, make, and use Idenix's invention." (D.I. No. 454-5 (Idenix Opp. to Gilead MIL No. 2) at 3.) Importantly, it is undisputed that if Pharmasset copied anything—which it did not—it did not copy Idenix's 2'methyl-up, OH down compound. Rather, it is alleged only that 2'methyl up—a *feature* of the claimed compounds—was copied. Idenix does not assert that Pharmasset copied the use of fluoro, or anything else, at the 2' down position. For example, Dr. Sommadossi testified [redacted] (Warden Decl. Ex. 3 at 68:6-14.) And, in Idenix's opposition to Gilead's Motion *in Limine* Number 2—directed to excluding evidence regarding the alleged "copying"—Idenix asserts only that Dr. Schinazi learned about "a key 2'-methyl 'up' modification," which "Pharmasset then copied." (*See* D.I. No. 454-5 (Idenix Opp. to Gilead's MIL No. 2) at 2.) Thus, Idenix does not allege that Pharmasset copied its compound. Idenix does not allege that Pharmasset copied any product. Idenix alleges that, at most, Pharmasset copied "a modification"—in essence, a feature, and Federal Circuit "case law holds that copying requires evidence of efforts to replicate a *specific product*." *Wyers v. Master Lock Co.*, 616 F.2d 1231, 1246 (Fed. Cir. 2010) (emphasis added).

There can be no dispute any longer that 2'methyl up alone is Idenix's alleged invention. The Court ruled just this Wednesday that Idenix's invention is *not any* 2' methyl or 2' methyl up—rather "effective amount" now imposes structural limitations on the compounds which fall

within the scope of the claims. Therefore, Idenix's expert, Dr. Meier, will be allowed to testify that only a small subset of ***specific*** 2'methyl compounds is in fact covered. (*See* D.I. 431 at 10.) Thus, 2'methyl up, by itself, is not an embodiment and evidence regarding Pharmasset's alleged "copying" of 2'methyl up—even if true and even if taking place in the right time frame (which it did not)—can have no bearing on whether Idenix's patent describes or enables what Idenix now claims. *See Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1366 (Fed. Cir. 2001) ("First, we note that evidence of copying Amazon's '1-Click®' feature is legally irrelevant unless the '1-Click®' feature is shown to be an embodiment of the claims."); *Leapfrog Enterprises, Inc. v. Fisher-Price, Inc.*, 2005 WL 1331216 (D. Del. June 6, 2006) (relying on *Amazon.com* to hold that "evidence of copying [the patentee's product] is legally irrelevant unless the [product] is shown to be an embodiment of the claims"); *ICU Medical, Inc. v. RyMed Techs., Inc.*, 752 F. Supp. 3d 486, 493 (D. Del. 2010) (holding that evidence of copying was not relevant to validity or willfulness when plaintiff "d[id] not contend that the earlier [copied] device embodie[d] any of the asserted claims in the patents at issue").

To allow Idenix to present evidence of alleged "copying" of a feature that does not constitute an embodiment of the claims cannot enhance the jury's ability to decide the threshold liability issues and in fact will invite exactly the wrong Section 112 analysis. Under very similar circumstances, this Court recently elected to phase trial due to the risk of unfair prejudice to the defendant if evidence relevant to willfulness was presented during the liability phase of trial. *See 3M v. Andover*, C.A. No. 13-843-LPS, Oct. 28, 2016 Hearing Tr. (Warden Decl. Ex. 4). There, this Court explained that, absent phasing, there was risk that the defendant would be "unfairly prejudiced by what would be mostly or entirely irrelevant evidence and argument affecting the jury's analysis of issues of liability," including "evidence about the parties' relationships about

copying." (*Id.* at 54:2-6, 17-18.) Notably, by contrast, this court found "no real cognizable prejudice to [plaintiff] from the phasing decision." (*Id.* at 55:11-15.) Likewise, here, there would be no cognizable prejudice to Idenix in phasing, which will still result in the same jury deciding both liability and (if necessary) damages during the same two weeks that would be used for an unphased trial.

When faced with similar concerns, other courts have also bifurcated or phased trial. *See, e.g., Princeton Biochemicals*, 180 F.R.D. at 258 ("Willful infringement is more appropriately determined after liability has been established, thereby avoiding even the possibility of prejudice to a patent defendant's litigation rights."); *B. Braun Med. Inc. v. Abbott Labs.*, 1994 WL 468155, at *1 (E.D. Pa. Aug. 29, 1994) (holding that "judicial convenience will be served by trying damages and willfulness separately from liability"); *see also Johns Hopkins University v. Cellpro*, 160 F.R.D. 30, 33 and 36 (D. Del. 1995) (noting the incidental benefit of bifurcation to defer willfulness as well as damages until after liability issues are decided). Thus, as this Court did in *3M*, where the circumstances were unusual as in this case, it should phase trial so as to avoid unfair prejudice to Gilead that would result in the presentation of evidence relevant, at most, to willfulness while the jury is still tasked with deciding the validity of Idenix's patents.

B. Phasing Trial Will Enhance Juror Comprehension

Patent cases by their very nature involve complex technical issues. In considering bifurcating trial in patent cases, this district has found that:

> Aside from the burden imposed on the court, the burden imposed on a jury in a patent trial is extraordinary. More specifically, juries are tasked with resolving complex technical issues regarding infringement and invalidity, many times with respect to multiple patents and/or multiple prior art references. Absent bifurcation, jurors then are expected to understand the commercial complexities of the relevant market (or, even more impenetrable, the commercial complexities of the hypothetical market) in order to determine the economic consequences of their liability decisions.

Robert Bosch, 2009 WL 2742750, at *1; *see also Ciena*, 210 F.R.D. at 521 ("[Phasing trial] might also enhance jury decision making in two ways: (1) by presenting evidence in a manner that is easier for the jurors to understand, and (2) by limiting the number of legal issues the jury must address at a particular time.").

These concerns are particularly applicable here. The liability phase of this case will focus not only on the complex chemistry underpinning drug development, but also on complex legal issues, including section 112 defenses. That task would be made more difficult if the jury were also asked to take on the additional burden of reviewing evidence regarding two competing, and very different, sets of damages scenarios and regarding evidence directed to whether Gilead behaved in an allegedly egregious manner in its development of the accused products. Again, this is not a run of the mill case; the scientific and legal issues are particularly complicated and the damages demand is extraordinary. Although it is certainly the case that juries are capable of understanding and deciding complex scientific and legal questions, as this Court recognized in the *3M* case, "there is some risk" of jury confusion and when that risk is factored into "the overall balance, including . . . a lack of prejudice to the plaintiff from the bifurcation" there is no "reason to take that risk, whatever degree it is." (Warden Decl. Ex. 4 at 58:1-8.)

C. Phasing Trial Will Promote Judicial Economy and Efficiency Because There Is Little Overlap Between Liability and Damages/Willfulness Issues

Phasing trial to separate the liability issues and willfulness/damages issues would conserve judicial resources by potentially avoiding unnecessary trial testimony and evidence related to damages and willful infringement if the jury finds that the patent-in-suit is invalid.

First, the logistics of phasing the trial should not be difficult. Just as this Court ordered done in *3M*, or as the California court did in the Merck case, issues of alleged liability can be

separated from issues of alleged damages and willfulness because, as discussed above, proof of damages is largely independent of proof of liability, and willfulness logically should be tried with damages. *See, e.g., Robert Bosch*, 2009 WL 2742750, at *1 (bifurcating liability from damages and willfulness issues and finding that "willfulness is a damages issue, not a liability issue"); *Ciena Corp.*, 210 F.R.D. at 521; *Yamaha Hatsudoki Kabushiki Kaisha v. Bombardier, Inc.*, 2001 WL 501354, at *3 (C.D. Cal. May 4, 2001) ("[T]he liability and damages issues are not so interwoven that one cannot be determined independently of the other"). At trial, the damages experts and damages-related fact witnesses would not have to testify until the second phase and the liability experts would no longer be needed in that phase. The trial is set for 10 days and there are now 16 claims (with only a few independent) of one patent at issue. Thus, there is sufficient time to allow for a second set of counsel argument and jury instructions.

Second, if there is no liability found, the potential savings of trial time would be substantial. *Lab. Skin Care*, 757 F. Supp. 2d at 442 ("Judicial resources may be conserved through bifurcation, as liability may not be found, or even if found it may simplify the subsequent damages and willfulness trial."); *Novopharm Ltd. v. Torpharm, Inc.*, 181 F.R.D. 308, 311 (E.D.N.C. 1998); *Eaton Corp. v. Auburn Gear, Inc.*, 1988 WL 273448, *3 (N.D. Ind. 1988). That potential savings of trial time was a motivating factor for this Court's decision to phase trial in *3M*. (Warden Decl. Ex. 4 at 54:24-5 ("[I]t is possible that we'll never reach Phase II, depending on the outcome of Phase I, and if that were to be the case, of course, that would create efficiencies for the Court and for the jury and arguably for the parties as well.").) Similarly, it was a motivating factor for the California court's decision to phase the Merck case. (Warden Decl. Ex. 2 at 5:14-17 (explaining that phasing "will have the benefit, I think, of potentially

simplifying the case because if the patents are deemed by the jury to be invalid, then we don't have a damages phase").) It should, likewise motivate the Court to phase this case.

V. CONCLUSION

For the foregoing reasons, Gilead respectfully requests that its motion for phased trial be granted.

Dated: November 18, 2016

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